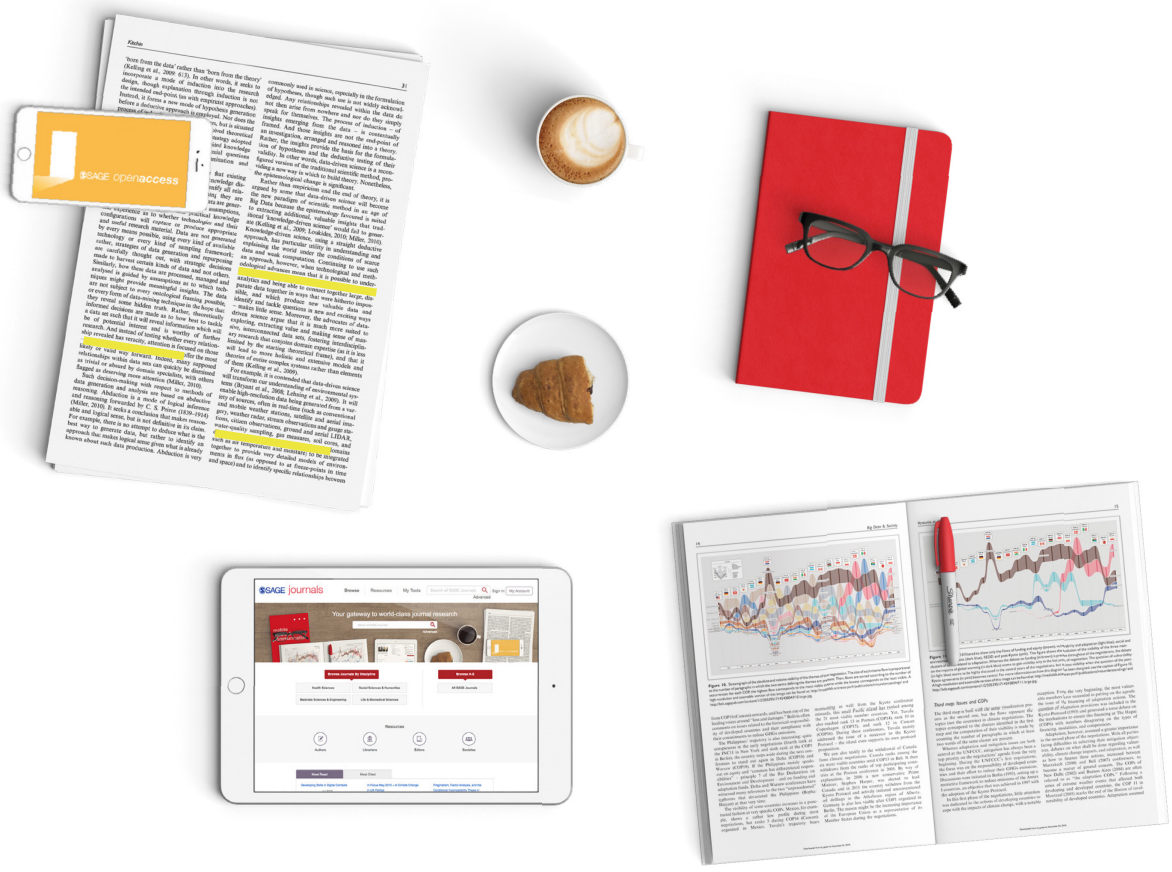


# Editor Guidelines

## Ethics Approval and Informed Consent Statements

# Editor Guidelines: Ethics Approval and Informed Consent Statements

The inclusion of ethics approval and informed consent statements is a fundamental requirement for research articles, and a key responsibility for each handling Editor to uphold. SAGE has created these materials to assist Editors in ensuring that these statements are present and correct, and to ensure consistency of statements between and within journals. The inclusion of this information in a standardized way in every manuscript also facilitates the evaluation of journals by abstracting & indexing services.

SAGE's standard policy for journals publishing human and/or animal studies is to require every manuscript—including non-research papers—to include appropriate statements on the following:

> **(1) Ethics committee, institutional review board (IRB) or institutional animal care and use committee (IACUC) consideration.**
> **(2) Informed consent (for inclusion, collection/use of data or samples, and/or publication, as applicable) or, in the case of animal studies, animal welfare.**

## Editor and author responsibilities

It is the author's responsibility to provide accurate and complete reporting; it is one of the responsibilities of the handling Editor to check that papers submitted to peer review and accepted for publication in their journal contain appropriate ethics and consent/animal welfare statements that are clear to an international readership.

Owing to potential differences in requirements for ethics approval and informed consent between countries and between institutions for various study types, the guiding principle is that—unless journals have an alternative policy in place—Editors may follow the requirements and legislation in the country or region in which the study was conducted, so long as sufficient detail is included. Editors should request more information from authors if the statements that have been provided do not specify why a particular course of action was taken. Some common issues are discussed in Appendix A.

Authors are required to confirm that the appropriate ethics review and informed consent/animal welfare protocols have been followed. Where applicable, authors are also expected to have conducted their research in accordance with the World Medical Association Declaration of Helsinki. Authors should not, as a matter of course, submit ethics approval or consent forms to the journal. In the rare event that an Editor suspects that there is a problem with ethical aspects of submitted work, they should liaise with their SAGE contact to request the relevant documentation from the author. If the forms are submitted, it is the Editor's responsibility to check thoroughly that they are appropriate. However, there are potential legal/privacy issues with journals receiving confidential patient information such as completed consent forms. Editors should seek assistance from their SAGE contact in such instances.

**Appropriate ethics approval and informed consent/animal welfare statements**

With regard to what constitutes appropriate ethics and consent/animal welfare statements, transparency and completeness are key. SAGE journals have international scopes and readerships, so what may be obvious and applicable in one country might not be the case in another. Editors are reminded of the following:

- Where ethics approval has been obtained, the name of the approving body and the approval number/ID should be included in the manuscript. It is preferable for authors to include more detail than, for example, "Approval was obtained from the local ethics committee."
- Where exemption from ethics approval has been granted by an appropriate body, this should be specified and the reason for exemption should be provided.
- Manuscripts should include statements that provide a clear explanation as to why ethics approval and/or informed consent was not sought for a given study in a specific country or region. Statements such as "Ethics approval was not required for this study" or "Not applicable" do not provide a sufficient amount of detail; suitable reasons, and citations where applicable, should be provided.
- Where informed consent has been obtained, it should be specified what the consent was for. For example, consent for treatment does not necessarily cover use of samples and/or inclusion in a retrospective study. In addition, consent for treatment is distinct from consent for publication of patient information (including images) in a case report, unless otherwise specified.
- It should be stated whether informed consent was written or verbal, and if the latter why that was the case (plus how the consent was recorded).
- Where applicable, authors should specify who waived the need for informed consent and state the reason.
- It is standard SAGE policy to require informed consent for the publication of case reports and case series deemed not to constitute research, except in exceptional circumstances or when waived by ethics committee/IRB or other authorized body. Even then, for completeness, Editors may wish to request consent for publication before considering a case report or non-research case series.
- Statements on animal welfare should confirm that the study followed international, national and/or institutional guidelines for humane animal treatment and complied with relevant legislation; that it involved client-owned animals and demonstrated a high standard (best practice) of veterinary care and involved informed client consent; or that guidelines for humane animal treatment did not apply to the present study, including the reason.

Please see Appendix A for more information and examples of appropriate statements.

Authors should provide statements on ethics approval and informed consent that conform to one of the following actions: obtained, exempted/waived or not sought/obtained. Detail of what is required can be found in the **Flowcharts** document, which contains visual guides for different study and article types. SAGE advises that manuscripts should not enter peer review or undergo editorial consideration without full statements in place. Editors using the flowcharts should identify the study/article type and follow the steps to determine whether adequate statements have been included or if additional information should be requested from the author. Editors should request assistance from their SAGE contact if they are unsure of how to proceed.

**Requesting additional information from authors**

Appendix B contains template text for requesting more information from authors when necessary. If Editors feel that the information provided in a manuscript is not clear or not adequate for an international readership, they should unsubmit the manuscript and request more detail from the author before the manuscript enters peer review or undergoes editorial consideration. If an Editor has any concerns over ethical procedures, they should reserve the right to reject papers—subject to appropriate investigation in conjunction with their SAGE contact and following the relevant Committee on Publication Ethics (COPE) guidance.

There may be exceptions to the information provided in these resources. Editors should be satisfied that the ethics approval and informed consent/animal welfare statements are appropriate for the study/article type.

# Appendix A: Common Issues and Example Statements

**What consent is needed for human and in vitro studies?**
Depending on the type of investigation, informed consent may be required for inclusion in and/or collection/use of data/samples for the present study (and potentially for publication if detailed, individual patient information is included). This type of consent is distinct from consent for treatment unless otherwise specified. Consent must be from the participant(s) or their guardian(s)/legally authorized representative(s) (including "gatekeepers" in the case of cluster randomized trials), if applicable. Assent should also be obtained from older children whose guardians/legally authorized representatives have given written informed consent.

**Is ethics approval and/or informed consent needed for retrospective studies?**
Retrospective studies may or may not require ethics committee/IRB approval and informed consent, depending on their nature and where they were conducted. Editors may follow the requirements and legislation in the country or region in which the study was conducted, so long as the authors include sufficient detail for the situation to be understood by an international readership who might not be familiar with regulations in that location.

**Is ethics approval and/or informed consent needed for clinical audits and service evaluations?**
Clinical audits and service evaluations may not require ethics committee/IRB approval because they do not constitute research where they were conducted. Editors may follow the requirements and legislation in the country or region in which the audit or service evaluation took place, so long as the authors include sufficient detail for the situation to be understood by an international readership who might not be familiar with regulations in that location. Regardless of whether approval was needed, ethical principles should have been followed, and informed consent may have been required.

**What consent is needed for case reports and case series?**
Case reports and case series deemed not to constitute research require informed consent specifically for the publication of patient information in the present manuscript. This is distinct from consent for treatment or participation in research unless otherwise specified. Consent must be from the patient(s) or their guardian(s)/legally authorized representative(s), if applicable. Assent should also be obtained from older children whose guardians/legally authorized representatives have given written informed consent.

**Is informed consent needed even if a case report has been anonymized?**
Although authors may feel that they have anonymized their case report so that it does not include any potential identifiers, in many cases anonymity cannot be guaranteed. It is standard SAGE policy to require informed consent for the publication of all case reports, except in exceptional circumstances or when waived by ethics committee/IRB or other authorized body. In the USA, for example, patient consent might not be required by an IRB for a case report because HIPAA compliance has been confirmed by the institutional Privacy Officer. Even then, for completeness, Editors may wish to request consent for publication before considering a case report.

- Exceptional circumstances would be (according to COPE): (1) if public interest considerations outweighed possible harms; (2) it was impossible to obtain consent; and (3) a reasonable individual would be unlikely to object to publication.

**Can ethics approval and informed consent be obtained retrospectively?**
Ethics committee/IRB review of research should not occur retrospectively. Similarly, informed consent for participation in research should be obtained before enrolment. However, patient consent for publication of a case report can be obtained after the report has been written, so long as it is done before the article is accepted.

**Does informed consent have to be written/when is verbal consent acceptable?**
In the majority of cases, informed consent is obtained in writing for participation in research and for publication of patient information in a case report. However, there are instances in which written consent might not be appropriate: for example, when the patient is illiterate or when a record of written consent could pose a danger to the individual. Ethics committee/IRB approval is usually required before verbal, rather than written, consent is obtained. Authors should provide sufficient detail regarding the reasons for verbal consent being obtained and state how the verbal consent was recorded.

**What is the distinction between a case report and a case series?**
The distinction varies widely. For the purposes of these resources, the following definitions are used:

*Case report:* Detailed report on an individual patient (e.g. presentation, diagnosis, treatment, response and follow-up).

- Ethics committee/IRB approval is often not required; consent should be obtained for publication of patient information.
- However, prospective research involving a single person does not qualify as a case report just because n=1.

*Case series:* Presentation of information on more than one patient.

- There are different definitions of when a case series becomes research (rather than being a case report of multiple patients) and, therefore, requires ethics committee/IRB review. In the USA, for example, some IRBs consider case series with n>3 to constitute research. If it is not clear whether a case series constituted research, SAGE advises Editors to liaise with the author and to follow the definitions in the country or institution in which the case series originated to ensure that appropriate ethics approval and informed consent statements are included.
- For case series deemed not to constitute research: ethics committee/IRB approval is often not required; consent should be obtained for publication of patient information.
- For case series deemed to constitute research: ethics committee/IRB approval may be required; consent may be required for inclusion in the study and for publication (e.g. if detailed, individual patient information is included).

**Is consent needed for publication of X-rays and scans?**
X-rays, scans and images of parts of the body do not usually require consent for publication, so long as there are no potentially identifying marks/features and no patient identifiers in the images or accompanying text.

**Examples of appropriate statements**

*Ethics approval obtained:*
This study was approved by the Mercy Health Research Ethics Committee (approval no. XYZ123).

*Exemption from ethics approval and waiver of informed consent granted:*
The Ethics Committee of the Hamburg Chamber of Physicians waived the need for ethics approval and the need to obtain consent for the collection, analysis and publication of the retrospectively obtained and anonymized data for this non-interventional study.

*Ethics approval and informed consent not sought:*
This study was approved by the Danish Data Protection Agency. According to Danish legislation, neither approval from the ethics committee nor informed consent from the study populations is required for registry linkage studies [23].

*Informed consent obtained for research:*
All participants provided written informed consent prior to enrolment in the study.

*Informed consent obtained for publication of a case report:*
Written informed consent was obtained from the patient for the publication of this case report.

*Verbal consent obtained:*
Informed consent was obtained verbally before participation. The consent was audio-recorded in the presence of an independent witness.

*IACUC approval obtained:*
The Dartmouth College Institutional Animal Care and Use Committee approved the experimental procedures (approval no. XYZ123).

*Animal welfare:*
All animal housing and experiments were conducted in strict accordance with the institutional Guidelines for Care and Use of Laboratory Animals.

# Appendix B: Template Text

The following sections provide some suggested template text for Editors requesting additional information from authors. Sections 1–8 are cited in the corresponding guides within the **Flowcharts** document. The text may be adapted as required.

## Section 1: "Human and in vitro studies" ethics approval

**Section A**

*Missing ethics approval statement:*

A statement on ethics approval is required in your manuscript. If ethics approval was obtained, please provide the name(s) of the ethics committee(s)/IRB(s) plus the approval number(s)/ID(s). If the study received exemption from ethics approval, please provide the name(s) of the ethics committee(s)/IRB(s) or other authorized body and the reason for exemption. If ethics approval was not sought for the present study, please specify why it was not required and cite the relevant guidelines or legislation where applicable, for the benefit of an international readership.

**Section B**

*Missing ethics committee/IRB name:*

In the ethics statement, please provide the name(s) of the ethics committee(s)/IRB(s) or other authorized body.

*Missing approval number/ID:*

In the ethics statement, please include the approval number(s)/ID(s).

*Missing reason for exemption:*

In the ethics statement, please include the reason for exemption from approval.

*Missing explanation of why ethics approval was not sought or citation of guidelines/legislation:*

In the ethics statement, please specify why ethics approval was not required and cite the relevant guidelines or legislation where applicable, for the benefit of an international readership.

## Section 2: “Human and in vitro studies” informed consent

**Section A**

*Missing informed consent statement:*

A statement on informed consent for inclusion in and/or collection/use of data/samples for the present study is required in your manuscript, even if the need for it was waived by ethics committee(s)/IRB(s) or it was not required according to relevant guidelines/legislation. If informed consent was obtained, please state whether it was written or verbal, and if the latter why that was the case in addition to how the consent was recorded. If the need for consent was waived by ethics committee(s)/IRB(s) or another authorized body, please specify this and include the reason for the waiver. If informed consent was not sought for the present study, please specify why it was not required and cite the relevant guidelines or legislation where applicable, for the benefit of an international readership.

**Section B**

*Missing explanation of why consent was verbal:*

In the informed consent statement, please specify why verbal (rather than written) consent was obtained.

*Missing explanation of how verbal consent was recorded:*

In the informed consent statement, please specify how the verbal consent was recorded.

*Missing ethics committee/IRB name and reason for waiver:*

In the informed consent statement, please provide the name of the ethics committee(s)/IRB(s) or other authorized body that waived the need for consent for the present study, in addition to the reason for the waiver.

*Missing explanation of why informed consent was not sought or citation of guidelines/legislation:*

In the informed consent statement, please specify why consent was not required for the present study and cite the relevant guidelines or legislation where applicable, for the benefit of an international readership.

## Section 3: “Case reports” ethics approval

**Section A**

*Missing ethics approval statement:*

A statement on ethics approval is required in your manuscript, for the benefit of an international readership. If ethics approval was obtained for the present report, please provide the name(s) of the ethics committee(s)/IRB(s) plus the approval number(s)/ID(s). If the report received exemption from ethics approval, please provide the name of the ethics committee(s)/IRB(s) or other authorized body and the reason for exemption. If ethics approval is not required for case reports or case series deemed not to constitute research at your institution, please specify this.

**Section B**

*Missing ethics committee/IRB name:*

In the ethics statement, please provide the name of the ethics committee(s)/IRB(s) or other authorized body.

*Missing approval number/ID:*

In the ethics statement, please include the approval number(s)/ID(s).

*Missing reason for exemption:*

In the ethics statement, please include the reason for exemption from approval.

*Missing explanation of why ethics approval was not sought:*

In the ethics statement, please specify why ethics approval was not required (e.g. ethics approval is not required for case reports or case series deemed not to constitute research at your institution).

## Section 4: “Case reports” informed consent

**Section A**

*Missing informed consent statement:*

A statement on informed consent for publication is required in your manuscript. Please confirm that the patient(s) or their guardian(s)/legally authorized representative(s) provided written informed consent for the publication of patient information in the present manuscript. If the consent was verbal, please state why written consent was not obtained, in addition to how the consent was recorded. If the need for consent was waived, please provide the name of the ethics committee(s)/IRB(s) or other authorized body, plus the reason for the waiver. If informed consent was not sought/obtained for the publication of patient information in the present manuscript, please specify why it was not obtained; however, please note that it is standard SAGE policy to require informed consent for the publication of patient information in case reports and case series deemed not to constitute research, except in exceptional circumstances or when waived by ethics committee/IRB or other authorized body.

**Section B**

*Missing explanation of why consent was verbal:*

In the informed consent statement, please specify why verbal (rather than written) consent was obtained.

*Missing explanation of how verbal consent was recorded:*

In the informed consent statement, please specify how the verbal consent was recorded.

*Missing ethics committee/IRB name and reason for waiver:*

In the informed consent statement, please provide the name of the ethics committee(s)/IRB(s) or other authorized body that waived the need for consent for the publication of patient information in the present manuscript, in addition to the reason for the waiver.

*Missing explanation of why informed consent was not sought/obtained:*

In the informed consent statement, please specify why consent was not obtained for the publication of patient information in the present manuscript; however, please note that it is standard SAGE policy to require informed consent for the publication of patient information in case reports and case series deemed not to constitute research, except in exceptional circumstances or when waived by ethics committee/IRB or other authorized body.

## Section 5: “Reviews and other” ethics approval

**Section A**

*Missing ethics approval statement:*

Although ethics approval may not be required for this article/study type, we request that authors provide a statement specifying this and giving a reason or listing the article type, in order to ensure complete transparency: for example, “Ethics approval was not required for this systematic review.”

**Section B**

*Missing reason:*

Although ethics approval may not be required for this article/study type, we request that authors provide a statement specifying this and giving a reason or listing the article type, in order to ensure complete transparency: for example, “Ethics approval was not required for this systematic review.”

## Section 6: “Reviews and other” informed consent

**Section A**

*Missing informed consent statement:*

Although informed consent may not be required for this article/study type, we request that authors provide a statement specifying this and giving a reason or listing the article type, in order to ensure complete transparency: for example, “Informed consent was not required for this systematic review.”

**Section B**

*Missing reason:*

Although informed consent may not be required for this article/study type, we request that authors provide a statement specifying this and giving a reason or listing the article type, in order to ensure complete transparency: for example, “Informed consent was not required for this systematic review.”

## Section 7: “Animal studies” ethics approval

**Section A**

*Missing ethics approval statement:*

A statement on ethics approval is required in your manuscript. If approval was obtained, please provide the name(s) of the IACUC(s)/ethics committee(s) plus the approval number(s)/ID(s). If the study received exemption from approval, please provide the name(s) of the IACUC(s)/ethics committee(s) or other authorized body and the reason for exemption. If ethics approval was not sought for the present study, please specify why it was not required and, where applicable, cite the relevant guidelines or legislation, for the benefit of an international readership.

**Section B**

*Missing IACUC/ethics committee name:*

In the ethics statement, please provide the name(s) of the IACUC(s)/ethics committee(s) or other authorized body.

*Missing approval number/ID:*

In the ethics statement, please include the approval number(s)/ID(s).

*Missing reason for exemption:*

In the ethics statement, please include the reason for exemption from approval.

*Missing explanation of why ethics approval was not sought or citation of guidelines/legislation:*

In the ethics statement, please specify why ethics approval was not required and, where applicable, cite the relevant guidelines or legislation, for the benefit of an international readership.

## Section 8: “Animal studies” animal welfare

**Section A**

*Missing animal welfare statement*

A statement on animal welfare is required in your manuscript. Please confirm that (a) the present study followed international, national and/or institutional guidelines for humane animal treatment and complied with relevant legislation; (b) the present study involved client-owned animals and demonstrated a high standard (best practice) of veterinary care and involved informed client consent; or (c) guidelines for humane animal treatment did not apply to the present study (if this is the case, please provide an explanation).

**Section B**

*Missing statement on humane animal treatment:*

In the animal welfare statement, please confirm that the present study followed international, national and/or institutional guidelines for humane animal treatment and complied with relevant legislation.

*Missing statement regarding client-owned animals:*

In the animal welfare statement, please confirm that the present study demonstrated a high standard (best practice) of veterinary care and involved informed client consent.

*Missing explanation of why humane animal treatment guidelines did not apply:*

In the animal welfare statement, please explain why guidelines for humane animal treatment did not apply to the present study.